

Moldova Activities Coordination
Trip Report

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June 2004

Rational Pharmaceutical Management Plus Program
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This report was made possible through support provided by the U.S. Agency for International Development, under the terms of cooperative agreement number HRN-A-00-00-00016-00. The opinions expressed herein are those of the author(s) and do not necessarily reflect the views of the U.S. Agency for International Development.

About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Recommended Citation

Burn, Robert. 2004. *RPM Plus: Moldova Activities Coordination*. Submitted to the U.S. Agency for International Development by the Rational Pharmaceutical Management Plus Program. Arlington, VA: Management Sciences for Health.

Key Words

Tuberculosis, national tuberculosis program, tuberculosis drugs, drug management information system, management, multi-drug resistant tuberculosis, Moldova.

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Abstract

Tuberculosis is a growing health issue in Eastern Europe and an inexpensive and effective treatment regimen exists promulgated by World Health Organization (WHO). The United States Agency for International Development (USAID) is funding Rational Pharmaceutical Management Plus (RPM Plus) to strengthen the drug management aspects of national tuberculosis programs (NTPs). In October 2002, RPM Plus assessed drug management information needs for program managers and other stakeholders of the Moldova national tuberculosis program. Based on the findings of the assessment, a policy options workshop was held in April 2003. Stakeholders in the tuberculosis (TB) drug management information system (DMIS) reviewed the current status of TB DMIS, gained a better understanding of the DMIS issues facing the NTP and proposed future steps to strengthening the system. These steps include establishing drug management indicators, as a component of the GFATM project monitoring and evaluation system, for assessing the performance of this function of the NTP and guiding decisions for improvement. Since October 2003, RPM Plus, with the expertise of a local consultant hired in January 2004, has developed and agreed with counterparts upon a set of drug management indicators, and has begun the process of institutionalizing their implementation. In 2004, RPM Plus initiated technical assistance in pharmaceutical management for 2nd-line drugs, to complement the MOH and NTP's application to the Green Light Committee for support to the treatment of multi-drug resistant TB patients through a DOTS Plus program.

Acronyms

AIHA	American International Health Alliance
DMIS	drug management information system
DOTS	directly observed therapy short-course (WHO TB Control Strategy)
DOTS Plus	WHO MDR-TB control strategy
DTC	Drug and Therapeutics Committee
E&E	Europe and Eurasia (Bureau of USAID)
GDF	Global Drug Facility
GFATM	The Global Fund to Fight AIDS, Tuberculosis & Malaria
GLC	Green Light Committee
M&E	monitoring and evaluation
MDR-TB	multi-drug resistant tuberculosis
MOH	Ministry of Health of Moldova
MSH	Management Sciences for Health
NGO	Non-governmental organization
NTP	national tuberculosis program of Moldova
RPM Plus	Rational Pharmaceutical Management Plus Program [MSH]
SPCPHSM	Scientific Practical Center of Public Health and Sanitary Management
SO	strategic objective
TA	technical assistance
TB	tuberculosis
UNAIDS	United Nations Joint Program on AIDS
USAID	United States Agency for International Development
WHO	World Health Organization

Executive Summary

The RPM Plus program of Management Sciences for Health (MSH) assessed drug management information needs for program managers of the national tuberculosis program and other stakeholders in Moldova in October 2002. The assessment reviewed existing drug management information policies, procedures and capacity, identified information flows and means of communication and defined data and information gaps, leading to the development of recommendations for strengthening information and its use for decision-making.

Several national institutions and international organizations have a stake in data collection, analysis and reporting on the national tuberculosis program (NTP), with each having particular information needs. There are multiple sources of information for TB program management, the organization of information is fragmented, and the appropriate operational data required for drug management is not collected systematically. Gaps in the collection and analysis of data required for the optimum management of a drug supply system were identified. These findings supported the view that investment in the development of a consolidated DMIS would be beneficial to all stakeholders.

RPM Plus organized a workshop, *Informed Decision-Making for Drug and Supply Management within the National Tuberculosis Program: Current Status and Options for Strengthening*, in April, 2003, in Chisinau, with 40 participants from stakeholder organizations attending. By the close of the two-day event, the participants had an improved understanding of the strengths and weaknesses of the drug management information procedures and practices within the NTP and participated in an initial discussion on identifying and recommending options for strengthening informed decision-making for drug and supply management.

In July 2003, RPM Plus conducted follow-up discussions with the Ministry of Health (MOH) to determine the timing of the next step—a workshop to select drug management indicators to monitor performance and to review and re-design aspects of the DMIS to improve data collection, analysis and use in decision-making. RPM Plus' Monitoring and Evaluation Coordinator continued the discussion with the Manager of the NTP on drug management indicators, and reached agreement on an appropriate set to be implemented by the program.

In January 2004, MSH recruited a local pharmacist to provide a full time support to the RPM Plus activities in Moldova.

As part of MSH/RPM Plus collaboration with the World Health Organization (WHO) Global Drug Facility (GDF), RPM Plus jointly conducted a monitoring visit to Moldova to assess compliance with the conditions of the GDF support and to determine the program's 1st-line drug requirement for the next year.

The RPM Plus workplan for FY04 aims to support the program to treat multi-drug resistant TB (MDR-TB) cases through strengthening the management of 2nd line drugs and RPM Plus assisted the MOH to prepare its application to the Green Light Committee (GLC).

Background

The RPM Plus program, implemented by MSH, has received funds from the USAID Bureau for Europe and Eurasia for activities in the region which support the Bureau's strategic health objectives (SOs), including supporting countries to improve the control of TB. Tuberculosis is increasing in the region and the situation in Eastern Europe and the Newly Independent States is of particular concern. The number of reported tuberculosis patients in the WHO Europe Region rose from 280,000 in 1995 to over 373,000 in 2002¹.

Moldova initiated the directly observed therapy short-course (DOTS) strategy in three pilot areas—the municipality of Chisinau, and Orhei and Lapusna judets (counties)—in November 2001 and by January 2004 the DOTS strategy was implemented in all judets including Transnistria. The countywide adoption of the DOTS approach has been complimented by the agreement of the Global Drug Facility to provide first line anti-TB drugs for all DOTS areas. In January 2004 the GDF conducted a monitoring mission to review compliance with GDF grant conditions and, with the NTP, determined the drug requirements for the third year of support.

In 2001, the number of registered new TB patients increased by 33 percent over 2000, and in 2002 there were 4,149 registered cases. The expansion of DOTS, strengthened case finding and diagnostic practices, and sufficient availability of first-line TB drugs through the MOH central procurement and GDF assistance have all contributed to the increased registration of new patients. Drug resistant strains of tuberculosis are an increasing problem in Moldova with estimates that almost 40 percent of patients have developed resistance to at least one of the five main first-line drugs.² This resistance has arisen and evolved in parallel with the increasing failure of the TB drug management supply system to cover proper treatment in full. The MOH responded to this concern by tendering the first procurement for second-line drugs in fall 2002.

RPM Plus activities in Moldova during 2001–2002 were focused on strengthening tuberculosis drug management and on antimicrobial resistance. These activities included assessments of TB drug procurement and distribution practices, GDF assessments, a Drug and Therapeutics Committee (DTC) course in Moldova, and a regional training course on TB drug procurement held in Sinaia, Romania. RPM Plus prioritized the drug management information system (DMIS) as a key area to be strengthened following the assessment of tuberculosis drug procurement.

Centralization of anti-TB drug procurement has been evolving since 2001, with the MOH in the lead role as a policy and decision maker. At the same time, supply from the Global Drug Facility has dramatically improved anti-TB drugs availability and has provided a crucial opportunity for maintaining positive outcomes in TB control. With improved availability of anti-TB drugs, it is even more important that drug management capacity and practice be strengthened. The current multi-year support of the GDF provides the Moldova leadership with the opportunity to plan for sustaining a full supply situation into the future through reliance on internal resources and domestic capacity. Strengthening the TB DMIS to support decision-making is a key factor,

¹ WHO Global TB Control Report 2003.

² Zagorskiy, Andrey and Alix Beith. 2002 *RPM Plus Moldova Trip Report: Brief Assessment of Tuberculosis Drug Procurement in Moldova*.

along with the development of a full understanding of contemporary drug management practices, to the program's ability to manage anti-TB drugs in a systematic way that will ensure uninterrupted supply and 100 percent availability.

The NTP has made promising steps in reorganizing the distribution of TB drugs from the central store to a quarterly schedule, replacing the single annual issue procedure. In accordance with the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) monitoring requirements, the NTP is developing, with RPM Plus support, a set of drug management indicators, a sub-set of which will feed into the monitoring and evaluation scheme for the GFATM project.

The Ministry of Health and TB Institute are aware of the issue of multi-drug resistant TB, though there have been problems in financing and procuring adequate supplies of the expensive 2nd line drugs needed for MDR-TB treatment. Earlier in 2004 the MOH postponed a tender for 2nd line drugs and is aware of the WHO's recommendations that a strong DOTS program be in place to provide a foundation for any program to treat MDR-TB cases. Hence the MOH has decided to apply to the Green Light Committee for support and approval to purchase 2nd line drugs through the GLC mechanism.

Purpose of Trip

- (a) Work with TB Institute counterparts to draft the drug management component of the Moldova application to the Green Light Committee.
- (b) With the local consultant, work with the NTP to finalize the set of indicators for monitoring drug management activities within the NTP, and reach agreement with counterparts on what actions are required to implement these indicators.
- (c) Plan for future RPM Plus activities for the pharmaceutical management of second line drugs.

Scope of Work

- Brief/debrief the USAID Mission on the RPM Plus Program activities in Moldova
- Collaborate with counterparts on drafting of application to the Green Light Committee
- Finalize the selection and elaboration of key indicators for monitoring drug management within the national TB program
- Initiate design work on data collection forms, and data analysis and reporting processes for drug management indicators
- Plan future RPM Plus work plan activities with the NTP

Annex 1 contains a list of persons met during the TDY, and the full text of the Request for Country Clearance for this visit appears in Annex 2.

Activities

1. Provide briefing and/or debriefing to the USAID Mission, as requested.

Robert Burn, Senior Program Associate, and Ms. Rita Seicas, MSH Consultant, met at the USAID office in Chisinau with Mr. Mark Levinson, Program Development Officer, Mr. Vasile Filatov, Project Management Specialist, and Ms. Diana Cazacu, Project Management Assistant. The RPM Plus team debriefed USAID on progress, in particular regarding the collaboration with the National Tuberculosis Control Program/Institute of Phtysiopneumology on the preparation of the application to the Green Light Committee for support to the DOTS Plus program. They also advised USAID about plans to hold a meeting to initiate the implementation of the drug management indicators within the NTP and to conduct a course in Pharmaceutical Management for MDR-TB later this year which will directly support the proposed DOTS Plus program for the treatment of MDR-TB patients.

USAID was informed of Dr. Ciocanu's solicitation of financial support for the design and development of the monitoring and evaluation computer software. They suggested that there might be equivalent software available in other countries.

2. Collaborate with counterparts on drafting of application to the Green Light Committee

In recent years the Ministry of Health had been providing some treatment for MDR-TB patients, though the expensive drugs needed for MDR-TB treatment had not been available in sufficient or continuous supply from public funds. Also in light of WHO recommendations that a strong and effective DOTS program is a necessary precursor to a MDR-TB treatment program, the MOH had been dissuaded from further purchases of second-line drugs. Moldova has about 300 MDR-TB cases and in order to address their needs the MOH and TB Institute recognized the necessity to develop a formal DOTS Plus program, following WHO guidelines, and based on an application to the Green Light Committee for technical support and the opportunity to purchase lower-cost, quality second-line drugs through the GLC mechanism (with GFATM project funding).

The GLC requires that approved programs have the capacity to manage and monitor the supply and use of second-line drugs from receipt in country to consumption by the patient. Since MSH/RPM Plus had been working with the NTP on strengthening the drug management information system for the DOTS program, the NTP requested MSH/RPM Plus assistance in drafting the drug management section of the GLC application.

The RPM Plus team consulted with Dr. Sain, the manager of the NTP, and met with the Chief of the MDR-TB department at the hospital located at the Institute of Phtysiopneumology and the Chief Pharmacist at the hospital's storage facility to learn about the current procedures and practices for the control of 2nd line drugs. Using the information obtained from these sources, and the findings of a review of pharmaceutical management of 2nd line products, RPM Plus drafted text for inclusion in the application to the GLC. (This was subsequently reviewed by a consultant who was assisting the NTP with the complete application and incorporated into the document. See Annex 3 for details). The NTP submitted the application in July.

3. Finalize the selection and elaboration of key indicators for monitoring drug management within the national TB program

RPM Plus reaffirmed with Dr. Sain, the recently appointed Manager of the NTP, the list of proposed drug management indicators.

Dr. Ciocanu, Director of the Scientific Practical Center for Public Health and Sanitary Management (SPCPHSM), responsible for developing and implementing a monitoring and evaluation scheme for the GFATM grant (which supports project activities in TB as well as HIV/AIDS), convened a meeting of donors and interested parties (included UNAIDS and AIHA) to discuss the implementation of the monitoring and evaluation (M&E) system. Funding for the development and procurement of a computerized system was incomplete (UNAIDS was contributing \$10,000, AIHA \$30,000 and the GFATM project \$10,000) and Dr. Ciocanu sought contributions. The aim is to develop a custom software application to be installed on computers in 85 health facilities.

RPM Plus, through Ms. Seicas, has been involved in the discussions concerning the incorporation of a sub-set of the drug management indicators proposed for the NTP into this software. It was agreed that she would continue to be involved in the elaboration of the software, especially concerning the drug management indicators.

4. Initiate design work on data collection forms, and data analysis and reporting processes for drug management indicators

The RPM Plus team was unable to address this task because of the commitment to assist with the GLC application, though Robert Burn and Rita Seicas discussed how to approach this over the next few weeks.

5. Plan future RPM Plus work plan activities with the NTP

The FY03 activities proposed by RPM Plus to support the treatment of MDR-TB cases in Moldova were outlined to Dr. Timbalarui and Dr. Sain during separate meetings. Their initial responses were receptive to this work plan. Rita Seicas will continue these discussions and jointly reach agreement on suitable dates for the training course on Pharmaceutical Management for MDR-TB Treatment (September was proposed). RPM Plus is planning to hold this course in Romania for both Moldovan and Romanian participants.

Adjustments to Planned Activities and/or Additional Activities

RPM Plus met for discussions with staff of the American International Health Alliance's (AIHA) Strengthening Tuberculosis Control in Moldova Project to follow-up on the meeting held by Dr. Ciocanu (SPCPHSM). AIHA is contributing financially to the development of the monitoring software and RPM Plus, knowing that MSH had recently prepared tender documentation relating to software development, agreed to share this by assisting AIHA with their own tender process.

Through discussions with Dr. V. Crudu, Laboratory Specialist, AIHA Project, the RPM Plus team sought further information about the project in order to explore possible collaboration.

Collaborators and Partners

Dr. Tambalari, Director, Institute of Phtysiopneumology

Dr. Sain, Coordinator, National Tuberculosis Control Program

Dr. Viorel Soltan, Project Director, AIHA

Mr. Vasile Filatov, USAID Moldova, Project Manager

Next Steps

Immediate Follow-up Activities

1. The RPM Plus consultant will discuss with Thuridur Arnadottir (TB consultant) the proposed drug management section for the GLC application and finalize text.
2. Contribute towards the development of the software specification for the SPCPHSM monitoring and evaluation system.
3. Send software tender specification document to AIHA Project Director.

Important Upcoming Activities or Benchmarks in Program

1. Pharmaceutical Management for MDR-TB Treatment course for managers and physicians of the MDR-TB program, MOH procurement unit staff, and pharmacists in charge of drug supply.
2. Drug Management Indicator Working Group meeting to operationalise the agreed set of indicators for monitoring and evaluation of drug management within the national tuberculosis control program.

Annex 1. Persons Met

Persons met during TDY	
National Tuberculosis Control Programme/ Institute of Phtysiopneumology	Dr. Sain, National Manager NTP Professor Tambalari, Director Dr. Vangheli, Vice Director Dr. Claudia Bradisteanu, Chief MDR-TB Department Pharm. Anghelina Djugostran, Chief Hospital Pharmacy
Scientific Practical Center of Public Health and Sanitary Management	Dr. Mihai Ciocanu, Director Mr. Valerui Plesca, Statistics Monitoring and Evaluation Department
AIHA Project Office	Dr. Voltan Siorel, Project Director Ms. Ina Lisnic, Project Administrator Dr. Valeru Crudu, Laboratory and Surveillance Specialist
Project Coordination Unit, TB/AIDS Project in Moldova	Dr. Dumitru Laticevschi Dr. Victor Burinschi
USAID	Mr. Vasile Filatov, Project Management Specialist Mr. Mark Levinson, Deputy Country Program Officer Ms. Diana Cazacu, Project Management Assistant
RPM Plus Consultant	Ms. Rita Seicas

Annex 2. Request for Country Clearance

Request for Country Clearance

TO: Vasile Filatov, USAID/Moldova
Diana Cazacu, USAID/Moldova
Mark Levinson, USAID/Moldova
Veronica Mihailiuc, USAID/Moldova
Olena Radziyevska, USAID/Ukraine

FROM: Management Sciences for Health (MSH) Rational Pharmaceutical Management Plus (RPM Plus) Program

SUBJECT: Travel of MSH/RPM Plus Senior Program Associate Robert Burn to Chisinau, Moldova from June 5-11, 2004. RPM Plus Cooperative Agreement No.: HRN-A-00-00-00016-00

COPY: Anthony Boni/ Global HSPR/CTO RPM Plus
Marni Sommer/ USAID Washington
Julia Wallace/ USAID E&E Bureau
Douglas Keene, Director, MSH/RPM Plus Program
Andrey Zagorskiy, Project Manager for TB, MSH/RPM Plus Program

1. The RPM Plus Program requests country clearance for MSH/RPM Plus Senior Program Associate Robert Burn to Chisinau, Moldova from June 5-11, 2004.

2. Background:

Moldova has one of the highest rates of tuberculosis (TB) of the former Republics of the USSR. With assistance from the World Health Organization (WHO), the Stop TB Initiative, and USAID, the Ministry of Health (MOH) is currently implementing new approaches to tuberculosis (TB) control based on WHO recommendations. The MOH, recognizing that drug supply is a crucial element of the TB control strategy, sought assistance in improving TB drug management. Initially, RPM Plus conducted an assessment in 2002 which identified a number of areas where TB drug management information needs and practices could be strengthened. Subsequently, a policy workshop on strengthening the TB Drug Management Information System (DMIS) was held in April 2003, after which RPM Plus developed a set of steps for consideration by the MOH and National Tuberculosis Program (NTP). As a component of these steps, the NTP and RPM Plus identified a set of pharmaceutical indicators and discussed integrating these with the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) project's planned monitoring and evaluation (M&E) system.

In January 2004, MSH recruited a local pharmacist to provide full time technical and logistical support to the RPM Plus Program in-country for strengthening the pharmaceutical management of first and second line drugs for the TB control program.

Moldova has just been awarded a third year's grant from the Global Drug Facility for first line anti-TB drugs and is currently preparing an application to the Green Light Committee for second line pharmaceuticals.

3. Purpose of Proposed Visit:

- (a) Work with TB Institute counterparts to draft the drug management component of the Moldova application to the Green Light Committee.
- (b) With the local consultant, work with the NTP to finalize the set of indicators for monitoring drug management activities within the NTP, and reach agreement with counterparts on what actions are required to implement these indicators.
- (c) Plan for future RPM Plus activities for the pharmaceutical management of second line drugs.

4. Scope of work for Robert Burn for this visit is as follows:

For the RPM Plus/Moldova program:

- Brief/debrief the USAID Mission on the RPM Plus Program activities in Moldova
 - Collaborate with counterparts on drafting of application to the Green Light Committee
 - Finalize the selection and elaboration of key indicators for monitoring drug management within the national TB program
 - Initiate design work on data collection forms, and data analysis and reporting processes for drug management indicators
 - Plan future RPM Plus work plan activities with the NTP
5. Anticipated contacts: Mr. Vasile Filatov (USAID/Moldova); Dr. Turcanu, First Vice Minister and other officials and specialists from the Moldovan Ministry of Health; Dr. Sain, (National TB Program); Professor Țâmbalari (National TB Institute); Dr. Dumitru Laticevschi, GFATM, and other donor agencies and country program representatives.
 6. Logistics: Robert Burn will arrive in Chisinau on Saturday June 5, 2004 and depart Moldova on Thursday June 10, 2004. No Mission assistance is required.
 7. Funding: RPM Plus is taking advantage of Mr. Burn being in Europe for a WHO-funded workshop to undertake this short visit to Moldova. The in-country RPM Plus work will be paid for with USAID/Moldova Mission and E&E Regional funds.

8. Action: Please advise Anthony Boni of country clearance for Robert Burn to travel to Moldova as planned. Please reply via e-mail to the attention of Anthony Boni, USAID/G/PHN/HN/HPSR tel. (202) 712-4789, fax (202) 216-3702, e-mail address aboni@usaid.gov. Please send carbon copies to Marni Sommer at msommer@usaid.gov, Andrey Zagorskiy at azagorskiy@msh.org, Robert Burn at rburn@msh.org, Douglas Keene at dkeene@msh.org and Meriel Jimenez at mjimenez@msh.org. Thank you in advance for Mission cooperation.

Annex 3: Extract from application to the Green Light Committee

Annex 12

Draft proposal for drug management in a DOTS-Plus pilot project in Moldova

NOTE: This proposal was provided by MSH and discussed and modified in the working group drafting the GLC application

1. Drug management

The DOTS-Plus pilot in Moldova aims to treat 100 MDR-TB patients. This is a small number of patients and the existing public health drug distribution system will be used to supply prescribed medicines, augmented where necessary to ensure full and complete tracking of second-line anti-TB pharmaceuticals. Modifications to the current system will be designed to be sustainable and thus continue to be implemented for MDR-TB patient treatment in the years to come.

Currently MDR-TB patients are located in all of the 40 “raions” (administrative sub-divisions of the country) and in Chisinau and Balti municipalities, but strict recruitment criteria will be used to enroll patients on treatment with second-line drugs in the DOTS-Plus pilot project.

Treatment regimen: The National Tuberculosis Program (NTP) has selected a standardized regimen³, consisting of Kanamycin, Ethoinamide, Ofloxacin, Cycloserine and Pyrazinamide (including Ethambutol only if supported by DST). The first five drugs (plus / minus Ethambutol) are prescribed for six months for the intensive phase (daily except for Kanamycin which will be administered daily six days a week for three months and then three times a week) and the same set—less Kanamycin and Pyrazinamide for 18 months in the continuation phase. PAS and Capreomycin will be used as reserve drugs in case of severe adverse reactions or absolute contraindications. The Ministry of Health (MOH) plans procure these drugs through the grant from the Global Fund to Fight AIDS, TB and Malaria, and therefore through the Green Light Committee mechanism.

The quality of second-line drugs for the DOTS-Plus project will be assured by the IDA procurement process and by usual, mandatory, testing on arrival of the consignment in Moldova. Existing storage capacity in the health system will ensure that the quality does not deteriorate during the period between receipt by the NTP and consumption by the patient.

Drugs for supportive or ancillary therapy for MDR-TB patients will be provided through the budget of the DOTS-Plus pilot project and funded from GFATM.

³ Guidelines for Establishing DOTS-Plus Pilot Projects for the Management of Multidrug-Resistant Tuberculosis (MDR-TB), WHO, 2000; and Treatment of Tuberculosis: Guidelines for National Programmes, WHO 2003.

Drug registration: Of the 25 products listed in the GLC Product Information Sheets⁴ as available through the GLC mechanism those currently registered in Moldova are listed at the end of this annex. In case a drug is needed which is not registered, this situation will be managed by the MOH through (1) the convening of a special commission to issue a waiver to allow for the importation of specific unregistered drugs needed for health programs of agreed importance (this arrangement is in line with steps undertaken by the MOH in order to import drugs donated by the Global Drug Facility for first-line treatment of TB for the DOTS program), and (2) by facilitation of registration of each unregistered product procured by the appropriate authorities in Moldova.

Importation and Customs Clearance: The MOH will enter into an agreement with the para-statal importer/distributor, San Farm Prim, to handle the importation of the second-line drug consignment, convey the consignment to the San Farm Prim warehouse in Chisinau, arrange quality testing, and store the drugs pending results of testing. San Farm Prim has been managing the importation and issue of the GDF first-line anti-TB drugs on behalf of the NTP for the last three years and is therefore fully conversant with governmental requirements and procedures. Any customs charges will be financed by the Government or waived.

Since the consignment of second-line drugs for the cohort of 100 MDR-TB cases is small in volume (in comparison with the GDF donations) and will be used only under the DOTS-Plus pilot project, distribution of the drugs will be strictly managed by the NTP. Therefore the entire consignment will be transferred, on completion of importation procedures, and upon the authorization of the MOH, to the pharmacy of the Pneumophthiology Institute (PPI) in Chisinau. It is proposed to identify the GLC procured products distinctively (or uniquely) to facilitate their control by the use of pre-printed, adhesive labels (or a specially designed ink stamp).

Central storage: As is current practice for the GDF drugs, separate records in the pharmacy stock register will be established for the GLC sourced second-line drugs to record receipts, issues to the MDR department and other TB cabinets (for PHC units) managing continuation phase of treatment on ambulatory basis, stock levels, and facilitate reporting to appropriate authorities in the NTP. Specifically, on a quarterly basis, reports will be prepared by the pharmacist and submitted to the NTP Manager indicating current stocks, quantities issued (by recipient department and “raion”), expiry dates, etc. These reports will be reviewed in conjunction with patient records to validate the movement of stock.

Transfer of stock to health facilities: Treatment of the intensive phase for all cases in the cohort will take place within the MDR-TB department in the PPI in Chisinau. Both for the intensive phase (at the PPI) and for the continuation phase (managed at the “raion” level) issues of second-line drugs by the pharmacist are only made on the basis of appropriate authorization. Issues will be made on a weekly basis for the MDR department and on a regular schedule every quarter for the “raions”.

The NTP plans to introduce an innovative system for the individualized management of the drugs required by each MDR-TB patient, in the continuation phase. The pharmacist will,

⁴ Procurement Manual for the DOTS-Plus Projects Approved by the Green Light Committee (WHO/HTM/TB/2003.328), WHO, October 2003.

following the instructions of the TB specialist determining the exact regimen for each case, assemble the second-line drugs needed for each patient for three months into a *patient pack*, labeling the package individually and specifically for each patient.

The *patient pack* will be transferred to the “raion” level on a regular schedule, in order to prevent disruption in the availability of medicines. Handling of drugs will be minimized and accountability simplified through the implementation of the *patient pack* system and monitoring DOT compliance facilitated by direct review of the contents of the pack.

The recording of DOT administered drugs at the “raion” health facility will be carried out using a monitoring form based on the principles of, and adapted from the standard TB01 form (see MDR-TB Treatment Card in Annex 7).

2. Patient Package

The NTP plans to introduce an innovative system for the individualized management of the drugs required by each MDR-TB patient, in the continuation phase. The pharmacist will, following the instructions of the TB specialist determining the exact regimen, assemble the second-line drugs needed for each patient for three months, labeling the accumulated package according to the patient identification.

Advantages

- Patient package assembled centrally by qualified, professional pharmacist under direction of senior NTP staff
- Drug needs in response to changes in regimen ensured centrally by supervising TB specialists
- MDR-TB patient is assured of continuity of supply from the commencement of the treatment course
- Patient package can move (between health facilities) if patient moves around the country
- Simplifies inventory control between the PPI pharmacy and “raion”
- Incompletely consumed package (demise of patient, defaulter, emigration, etc.) is returned to the PPI pharmacy for other re-supply needs
- Reduces handling of drugs and blisters
- Doesn't rely on the periphery to quantify re-supply needs
- Second-line drugs are well protected in transit.

Characteristics of system

- Pack contents assembled for 3 months supply of second-line anti-TB drugs
- Pack identified for specific patient (and location of patient, health facility)
- On commencement of the ambulatory phase of treatment 3 months supply is transferred to patient location
- Subsequent re-supply is in pack containing 3months requirements (providing re-supply is scheduled for quarterly)

Annex 4: A list of registered second-line anti TB drugs in Moldova

Nr. o/o	Int. Non-proprietary Name	Strength	Brand name of registered drugs	Manufacture and country of origin
1.	Amicacin	Powder for injection 250 mg .	Amicacin –KMP	Kievmedpreparat, Ukraina
2.	Capreomicin	-	-	-
3.	Ciprofloxacin	250 mg tablets	Ciprinol Cifloxinal Cebect-250 Ciprofloxacin 250 Lisproquin 250 Cifran 250 Ciprowin 250 Ultraflo-250 Microflon Cefan-250 Ciprofloxacin Ciprol	KRKA Slovenia Pro Med CS, Czech Republic Plethico, Pharmaceuticals, India Hau Giang United, Vietnam Lyka Labs Lt., India Ranbaxy, India Alembic, India Bal Pharma, India Mirco Nova, India Bombay Tablet, India Nature Product Europe, Holland Bosnalijek, Bosnia si Hertogovina
4.	Ciprofloxacin	500 mg tab.	Ciprinol Ciprofloxacin Cipromex 500 Cebect 500 Lyproquin 500 Cifran 500 Cifran 500 Ciprowin 500 Microflox Ciprofloxacin Ciprofloxacin Ciprodac 500 Ciprolox 500 Ciprol	KRKA Slovenia Hau Giang United, Vietnam Hau Giang United, Vietnam Plethico Pharmaceuticals, India Lyca Labs Ltd., India Ranbaxy, India Bombay Tablet, India Alembic, India Micro Nova, India Intermed, India Natur Product Europe, Holland Cadila, India Inter Pharma, India Bosnalijek, Bosnia and Hertogovina
Nr. o/o	Int. Non-proprietary Name	Strength	Brand name of registered drugs	Manufacture and country of origin
5	Etionamid	250 mg tab.		The application for registration from the manufacture Macleod,s India was examined by Drugs Commission, of the National Pharmaceutical Institute on 12.06.2004.
6.	Cycloserin	250 mg capsules		The application for registration from the manufacture Macleod,s

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				India was examined by Drugs Commission, of the National Pharmaceutical Institute on 12.06.2004.
7	Kanamicina	powder for injection 1 g	Kanamycin-KMP	Kievmedpreparat SAD, Ukraina
8	Ofloxacin	200 mg tab.	Ofloxacin	Hau Giang United, Vietnam
9	PAS	-	-	-
10	Pirazinamid	500 mg tab.	Pirazinamid	Holden Medical, Holland
			Pirazinamid	KRKA, Slovenia
			Pirazinamid	Imexpharm, Vietnam
			Pirazinamid	Antibiotice, Romania
			Pirazinamid	Ipca, India
		300 mg tab.	Pirazinamid	Euopharmaco, Moldova
11	Etambutol	400mg tab.	Etambutol	Holden Medical, Holland
			Etambutol	Imexpharm, Vietnam
			Etambutol	Antibiotice, Romania
			Etambutol	Ipca, India

Annex 5: Notes on the current situation of MDR-TB treatment in Moldova

- A number of MDR-TB patients were currently receiving treatment;
- Centrally procured Cycloserin was prescribed, though the other drugs needed had to be financed by the patient and purchased from the private sector, or in some instances funded by local health budgets;
- Several health reforms were affecting treatment:-
 - The recently inaugurated national health insurance scheme covers only 48 days of treatment during the intensive phase. The intensive phase usually lasts 6 months. 48 days has been determined from hospital records of the length of stay in 1999 (but one likely cause of under-reporting is the lack of drugs and hence unavailability of treatment in hospital):
 - The status of the Institute of Phthisiopneumology (as for all health institutions) is changing from public- to self-financing (which raises issues about whether the Institute would be responsible for 2nd line drugs in the continuation phase):
- Dr. Tambalari commented:-
 - that the GLC mechanism covered 2nd line drugs and not those drugs needed to manage adverse reactions;
 - that at a meeting with the MOH earlier in the year there had been spoken agreement that the MOH budget would fund the hospital stay for non-insured (80% of population are not insured);
- Dr. Sain commented:-
 - The Institute currently had 50 beds for MDR-TB cases;
 - The continuation phase of treatment could be as long as 18 months;
 - The commitment of the patient to continue treatment is obtained via a written document
 - District TB staff are informed of the discharge of a MDR-TB patient after the intensive, in hospital phase

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